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October 10, 2001

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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
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PETITION FOR RECONSIDERATION

The undersigned submits this petition for reconsideration of the Food and Drug Administration's denial of the request by Pharmanex, LLC (formerly Pharmanex, Inc., referred to in this memorandum as "I?harmanex") to export packaged Cholestin® and bulk red yeast rice currently in U.S. inventory.1

A. Decision Involved

By letter dated September 10, 2001, from Kevin M. Fain, Associate Chief Counsel for Enforcement, FDA, to Daniel A. Kracov, Counsel to Pharmanex, FDA has denied Pharmanex's request to export packaged Cholestin® and bulk red yeast rice inventory.

B. Action Requested

Pharmanex respectfully requests that the Commissioner permit the export of packaged Cholestin ® and bulk red yeast rice either as food or, in the alternative, as an unapproved new drug. In the alternative, FDA should utilize its enforcement discretion to pert-nit the export of the packaged Cholestin® and bulk red yeast rice inventory.

1 Letter from Kevin M. Fain, Associate Chief Counsel for Enforcement, FDA, to Daniel A. Kracov, Counsel to Pharmanex (September 10, 2001). Pharmanex's submissions to FDA in support of this position, and FDA's September 10,200 1, response, contain confidential commercial information.

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C. Statement of Grounds

I. Background

Pharmanex had been lawfully marketing Cholestin® as a dietary supplement in the U.S., and had been exporting the product from the U.S., when FDA decided on May 20, 1998, that Cholestin ® was excluded from the definition of "dietary supplement." FDA contended that, since that term excludes "an article that is approved as a new drug" and Cholestin ® contains lovastatin, Cholestin® does not fall under the deftition of "dietary supplement." FDA argued that "an article that is approved as a new drug" includes constituents as well as finished products. Pharmanex challenged FDA's determination that Cholestin ® does not meet the definition of "dietary supplement," by contending that the definition only refers to the finished drug product, and therefore, Cholestin ®, despite containing lovastatin, could still be considered a dietary supplement. The U.S. District Court in Utah agreed with Pharmanex's argument and concluded in 1998 that Cholestin® was, in fact, a dietary supplement. Pharmanex relied on the district court decision regarding the status of Cholestin® as a dietary supplement and continued importing the bulk red yeast rice used to produce Cholestin® for domestic marketing and for export.

On July 21, 2000, the U.S. Court of Appeals for the Tenth Circuit reversed the district court's decision. The court of appeals held that the deftition of "dietary supplement" is sufficiently ambiguous as to require deference to FDA's statutory interpretation, and remanded the case to the district court. Although the court of appeals decision addressed the statutory provisions at issue in the case, the court did not make a determination regarding the specific status of Cholestin® under those statutory provisions. It was not until the district court, in a March 30, 2001, opinion upholding FDA's determination that Cholestin ® is an unapproved new drug, that a definitive conclusion was reached by the courts regarding the regulatory status of the product. Consequently, it was not until March 30, 2001, that Pharmanex had definitive reason to cease marketing of Cholestin® as a dietary supplement.

II. Overview of Position

As explained herein, the packaged Cholestin® and bulk red yeast rice comply with the applicable export requirements and should be authorized for export either as food or, in the alternative, as an unapproved new drug. Regardless of the legal and regulatory

requirements associated with product export, however, the agency should recognize the unique equities presented by this case and utilize its enforcement discretion to permit the export of packaged Cholestin and bulk red yeast rice. Use of enforcement discretion in the instant case would be consistent with other examples of such agency discretion, and would also be consistent with public policy objectives intended to encourage – and not penalize – companies that reasonably rely upon judicial decisions and legal developments.

III. Packaged Cholestin ® and Bulk Red Yeast Rice Should be Permitted to Be Exported As Food

A. Packaged Cholestin® Satisfies the Requirements of Section 801(e)

1. Product Labeled for Sale in U.S.

FDA stated in its September 10, 2001, letter that Cholestin® labeled for sale in the U.S. cannot satisfy the requirements of Section 801 (e)(l) (C)-(D) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. $381 (e)(l)(C)-(D) that it be intended for export and not offered for sale in domestic commerce. The product was originally labeled for sale as a dietary supplement in the U.S. when such sale was lawful, and Pharmanex ceased marketing the product upon the March 30, 2001, ruling. Section 801 is satisfied by the present intent of the manufacturer to export the product at issue. Consideration of past sale of the product is irrelevant in this instance because, prior to March 30, 2001, there was one judicial decision that specifically addressed the legal status of Cholestin ®, *i.e.*, the district court decision in 1998, which held that it was a lawful dietary supplement. The court of appeals decision overturned the statutory basis for the district court decision, but left open other grounds for holding Cholestin® lawful.

FDA asserts, however, that since the language of Section 80 1 (e) (1) (D) uses the phrase "is offered" instead of "is being offered", it refers to both past and present instances in which the product is or was offered for sale in domestic commerce. The word "is" is defined in Webster's *Ninth New Collegiate Dictionary* in part as the present singular of "be" and as derived from words that mean "to be."[2] There is no reference to the past tense in the Webster's definition of the word "is." Although the term "is being offered for sale" specifically indicates applicability to the present tense, the term is not the exclusive means of stating that the requirement applies to the present, not the past. Furthermore, FDA, in

[2] Merriam-Webster Inc., Webster's *Ninth New collegiate Dictionary* (1986).

its draft "Guidance for Industry on: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996" stated that FDA examines whether the product "is sold or offered for sale in the U.S."[3] FDA does not state, however, that it will consider whether the product has been sold in the U.S. in the past. Although this guidance is only a draft document, it reflects the agency's interpretation of the statute, and FDA did not indicate that the requirement applies to past marketing. Consequently, because Section 801 (e)(I)(C) and (D) use the present tense, they only should be applied to this product as of the time it is exported. Thus, because the Cholestin® products in inventory have not been sold or offered for sale in the U.S. since the district court officially classified them as drugs, and will be labeled as intended for export if permitted to be exported, the products comply with Section 801(e) (l)(C) and (D).

FDA also indicated that Pharmanex failed to address the phrase "intended for export" at the beginning of Section 801(e)(l), 21 U.S.C. §381(e)(1). Weexplained in our April 25, 2001, letter that, as of the March 30, 2001, ruling regarding the status of Cholestin ®, Pharmanex no longer offered Cholestin® for sale in the U.S. Cholestin® product containing red yeast rice, as of March 30, 2001, was, and remains today, intended solely for export.

FDA expresses concern that our interpretation of Section 801(e) would undermine the purpose of the FFDCA because other manufacturers of adulterated, misbranded, or unapproved drug products could express a present intent to export a product whenever subject to FDA or judicial scrutiny. We strongly disagree. First, Pharmanex was exporting the product prior to the March 30, 2001 court decision. Second, Pharmanex made every effort to comply with all applicable provisions of the FFDCA, and in good faith presented a legitimate argument, accepted by a U.S. district court, supporting the status of Cholestin ® as a dietary supplement. Third, the specific articles proposed for export have not been sold or offered for sale in U.S. domestic commerce. Pharmanex fully understands and respects FDA's traditional policy, which does not normally permit a company to market a product in the U.S. in violation of applicable laws and regulations, and subsequently export the product. Here, however, the circumstances involving Cholestin ® and red yeast rice are unique and clearly distinguishable from traditional FDA export issues, and will not present a difficult precedent for the agency.

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[3] 63 Fed. Reg. 32219, 32223 (June 12, 1998).

2. Product Labeled for Sale in Japan

We provided evidence in letters of May 21, 2001, and August 14, 2001, clearly demonstrating that the product labeled for sale in Japan was intended for export to Japan when manufactured. It remains so intended today.

B. Bulk Red Yeast Rice Satisfies the Requirements of Section 801(e)

We maintain that the bulk red yeast rice, when imported, was lawfully characterized as a food and was labeled for use in food. Furthermore, the majority of the bulk red yeast rice was intended for export to Japan. Although FDA indicated that bulk red yeast rice is now considered a drug ingredient under the recent court decision, neither FDA nor the district court had specifically addressed the status of this bulk, unlabeled product. The status of red yeast rice, its intended use as a food, and clear regulatory status as a food in the country to which most of it was intended for export, should be considered by FDA when deciding whether to permit its export.

In its September 10, 2001, letter, FDA stated that, because bulk red yeast rice is intended as a component of Cholestin®, the rice itself is an unapproved new drug under Section 201(g)(1)(D) and Section 201(p), 21 U.S.C. §321 (g)(l)(D) and §321(p). However, despite FDA's classification of Cholestin® as a drug in the U.S., the bulk red yeast rice does not meet the definition of "drug." The inventory is a bulk substance in its present form, and will not be **further** processed in the U.S. prior to export. Given its intended use as a food in the countries of export, the bulk red yeast rice should not be considered a drug component.

In addition, sales figures from previous, regular exports from a seven month period should serve as adequate evidence of the intent to export the bulk red yeast rice in similar or greater amounts. A purchase order from Nu Skin Japan, Ltd, dated August 8, 2001, committing to purchase all of the red yeast rice in Pharmanex's inventory also clearly demonstrates the market for the product, indicates the intent to export the product, and further supports Pharmanex's position. Given that Pharmanex has ceased marketing Cholestin ® in the U.S., Pharrnanex would have no reason to deviate from its intention to export the remaining inventory. Pharmanex no longer has any domestic use for the bulk red yeast rice and should not be punished for maintaining its current inventory of the product. Pharmanex reasonably and justifiably relied on the 1998 district court decision in accumulating the inventory in order to lawfully manufacture a dietary supplement. In

any event, since Pharmanex has a long history of exporting the product at significant levels, it is inaccurate to suggest that all of the inventory of the bulk product used to manufacture the finished product was intended for domestic sale.

I-v. In the Alternative, Cholestin® and Raw Red Yeast Rice Comply With Section 802(f) and Should be Permitted for Export as Unapproved New Drug

FDA's September 10, 2001, letter states that product in inventory labeled for use in the U.S. and Japan and the bulk red yeast rice have not been demonstrated to be in substantial conformity with drug good manufacturing practices ("GMPs"), and therefore do not meet the requirements of Section 802, 21 U.S.C. §382. We urge the Agency to reconsider that conclusion.

A. Requirements of Section 802(f)

FDA claims that its draft Guidance for Industry on "Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996" states that the term "substantial conformity" means that "the firm must have passed its most recent [C]GMP inspection" or that any observed GMP violations have been corrected. As we noted in our April 25, 2001, letter, however, FDA acknowledges that "[n]either the 1996 Amendments nor its legislative history explains what constitutes 'substantial conformity' with cGMPs, but the legislative history for the Generic Drug Enforcement Act of 1992 may be instructive."[4] FDA goes on to cite that legislative history discussion of "substantial conformity" as suggesting that it "could not mean full compliance with GMPs."[5] FDA goes on to state in this draft guidance document its position on what the term "substantial compliance" means. This interpretation has been issued only in a draft document, however, and, as FDA states within the document, it "does not operate to bind FDA or the public."[6] This acknowledgment is especially important given the absence of a definition of what constitutes "substantial conformance" either in the statute or legislative history and the stated purpose of the legislation itself. The legislative history states that Section 802 was added to "make it easier to export drugs."[7] As we also pointed out in our April 25, 2001, letter, FDA has subsequently acknowledged that the FDA Export Reform and

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[4] 63 Fed. Reg. 32219, at 32226 (June 12, 1998).
[5] Id., citing H. Rep. No. 102-272 (1992)(emphasis added).
[6] Id., at 32219.
[7] 142 Cong. Rec. H40464 (April 25, 1996).

Enhancement Act of 1996 was enacted to simplify the requirements for exporting unapproved new drugs.8

Moreover, although the chapter of FDA's Regulatory Procedures Manual that we cited to support our position that complete compliance with GMPs is not necessary for drugs exported under Section 802 is part of the subchapter on "Import for Export", we believe that FDA's statements regarding these types of products are instructional for the situation at hand, particularly in light of the nature of the product, the intended use as a food in the countries to which the product is intended for export, and the lack of a definition of the term "substantial conformance" in the statute or in a final FDA document. Thus, we reassert that the Regulatory Procedures Manual, which states that if the drug exported "accords with the specifications of the foreign purchaser and is not in conflict with laws of the country to which it is exported," should apply as guidance for the situation involving Cholestin ®, and supports our position regarding the export of the Pharmanex inventory.

B. Compliance of Cholestin® with the Requirements of Section 802(f)

The documents and other information provided in our previous correspondence are adequate to support the conclusion that the packaged Cholestin® and bulk red yeast rice were produced in a manner that substantially conformed with drug GMPs.[9] In particular, the encapsulation and packaging of Cholestin® complied with the suggested enhanced GMPs for dietary supplements as set forth in the Advanced Notice of Proposed Rulemaking ("ANPR") at 62 Fed. Reg. 5699 (Feb. 6, 1997). Although the encapsulation and packaging did not meet drug GMPs *per se*, the enhanced ANPR GMPs applicable to the encapsulation and packaging operations for dietary supplements, which Cholestin® did meet, are substantially similar in most respects to the drug GMPs.

Prior registration of Pharmanex's contract manufacturer of Cholestin® and other elements of full compliance with GMPs should not be required for "substantial conformity" with drug GMPs. FDA acknowledges that the information Pharmanex has provided addresses some drug GMP requirements. Even if the information Pharmanex

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[8] 63 Fed. Reg. 32219, at 32220.

[9] The information we have provided includes: A Memorandum from the contract manufacturer of Cholestin® showing compliance with the proposed GMPs for dietary supplements; a Cholestin® Study Report prepared for filing in Taiwan; a Certificate of Analysis for Cholestin®, including results of testing for compliance with product specifications; the Cholestin® contract manufacturer's "'Process for Manufacturing of Cholestin® Japan;" and the Cholestin® contract manufacturer's "Standard Operating Procedures" for encapsulating products

has provided is not adequate to conclude that Cholestin® production complied with traditional GMPs applicable to drug products offered for sale in the **U.S.,** the information is sufficient to conclude that the product substantially conforms with GMPs. Furthermore, by separate submission we are providing to FDA, on a confidential basis, clarification of some of the information previously submitted, as well as additional information, to further support a determination of substantial conformitywith drug GMPs.

C. **Compliance** of **Bulk Red Yeast Rice with Section 802(f)**

FDA's September 10, 2001, letter states that Pharmanex has failed to show that the bulk red yeast rice was manufactured in substantial conformity with GMP requirements. We reiterate the ax-gun-rents set forth above and note that, particularly in the case of the bulk red yeast rice, strict adherence to drug GMPs is not required under Section 802(f).

V. FDA Should Utilize Its Enforcement Discretion to Permit the Export of Packaged Cholestin and Bulk Red Yeast Rice

Regardless of the legal and regulatory requirements associated with product export, FDA should utilize its enforcement discretion to permit the export of packaged Cholestin® and bulk red yeast rice.

A. Agency Enforcement Discretion

1. Judicial Recognition

The Supreme Court, in Heckler v. Chaney, held that there is a presumption that agency decisions not to initiate enforcement actions are not subject to judicial review.10 The Supreme Court, interpreting Sections 701-706 of the Administrative Procedure Act ("APA"), in which Congress established the rules governing judicial review of agency action and inaction, announced that if Congress has not indicated an intent to circumscribe agency enforcement discretion, and has not provided meaningful standards for defining the limits of that discretion, then "the agency refusal to institute proceedings is a decision 'committed to agency discretion by law' within the meaning of that section."11 The Supreme Court noted that it has historically "recognized...that an agency's

10 Heckler v. Chaney, 470 U.S. 821 (1985).
11 Id., at 835-836.

decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion," based on a number of reasons, including that the agency has special expertise to determine issues such as "whether agency resources are best spent on this violation or another...[and] whether the particular enforcement action requested best fits the agency's overall policies."[12] FDA's enforcement discretion is specifically reinforced by Section 309, 21 U.S.C. §336. Since the export provisions do not reflect Congressional intent to limit FDA's enforcement discretion, FDA's ability to exercise such discretion is clear, and Pharmanex asks the agency to consider that course in this instance.

2. The Circumstances Surrounding Cholestin® Warrant the Exercise of Enforcement Discretion

Given the unique circumstances of the Cholestin® product, it would be particularly appropriate for FDA to utilize its enforcement discretion by permitting the export of the inventory of Cholestin® and bulk red yeast rice, regardless of the agency's determinations regarding the technical compliance of the products with applicable export requirements. Pharmanex's reasonable reliance on a judicial determination regarding the status of the product, the distinctive facts of this situation, including the nature of the product, and its intended use after export, are compelling enough to justify FDA's exercise of enforcement discretion.

Pharmanex acted as a responsible company. It utilized the appropriate legal channels to resolve the issues of statutory interpretation and product status after lengthy discussions with FDA. The district court in Utah in 1998 agreed with Pharmanex's position that the product was, in fact, a dietary supplement. Consequently, Pharmanex was relying on the conclusion of the courts in support of continued lawful sale of the product as a food in the U.S. Even the July 21, 2000, decision of the U.S. Court of Appeals for the Tenth Circuit, did not conclusively classify Cholestin® as a drug. The fmal status of the product was not clear until the district court issued its opinion on March 30, 2001, upholding FDA's determination that, under the law, when applied to the facts of the case, Cholestin ® could be designated an unapproved drug by the agency. Pharmanex's reliance on the opinion of the court as the basis for continued marketing of the product as a dietary supplement in the U.S. was reasonable and justified, and Pharmanex should not be penalized for such good faith activities. Once the district court determined on remand on

[12] Id., at 831.

March 30, 2001, that the product was not a dietary supplement, Pharmanex again acted responsibly and promptly; it discontinued marketing of the product in the U.S. while segregating and holding all inventory pending discussions with FDA regarding export. Pharmanex further demonstrated its responsible action by ceasing the importation of additional bulk red yeast rice after the March 30, 2001 court of appeals decision. All of the bulk red yeast rice inventory at issue in Pharmanex's request for export was imported before the March 30, 2001 court of appeals decision.

It is also important to consider Pharmanex's history of exporting Cholestin® from the U.S. prior to March 30, 2001. We have provided FDA with detailed information regarding past exports of Cholestin® from the U.S., and pending orders for products currently in Pharamex's inventory in the U.S., in amounts that reflect past export practices. Pharmanex's request to export its current inventory of finished product and bulk red yeast rice is in keeping with the company's previous practice of exporting the product from the U.S. Consequently, the company's conduct is distinguishable from that of a company with no prior history of exporting their product that attempts to avoid the repercussions of agency enforcement action by exporting adulterated products from the U.S. for the first time.

FDA should also consider that the product is accepted in the countries to which it is proposed to be exported as a food product and meets all applicable requirements in those countries. As a result, FDA need not be concerned about the appropriateness or status of the product in the countries to which it would be exported, should FDA decide to exercise its enforcement discretion. There is no good reason for wasting this product, which, in the countries of export, would be used as a food.

FDA has stated that precedent and policy concerns justify its denial of Pharmanex's request to export the inventory. However, the agency has not raised any issues of public health that can be related directly to the Cholestin® finished product and bulk red yeast rice. Importantly, FDA has exercised its enforcement discretion in other situations that appear to present much clearer violations of FDA regulations, potentially significant safety and public health issues, and very serious policy concerns. One example of FDA's utilization of its enforcement discretion is its actions with respect to levothyroxine sodium; FDA announced in a recent guidance document that it plans to exercise its enforcement discretion with regard to levothyroxine sodium products that are marketed

without approved applications.[13] Levothyroxine sodium is a drug product used by approximately 10.5 million people in the U.S. who have diminished or absent thyroid function. FDA had announced on August 14, 1997, that orally administered levothyroxine sodium drug products are new drugs and that manufacturers are required to obtain approval of applications if they wished to continue marketing those products.[14] FDA then stated that, after August 14, 2000, any orally administered drug product containing levothyroxine sodium that is introduced or delivered for introduction into interstate commerce without an approved application would be subject to regulatory action. FDA later extended the deadline for obtaining approval until August 14, 2001.[15] However, FDA has recently revealed that it will be exercising its enforcement discretion by establishing a gradual phase-out of the unapproved products, and not taking action against manufacturers for marketing without an approved application if the manufacturer complies with the phase-out plan.

In the case of one particular product, Synthroid®, FDA employed its enforcement discretion to phase-out production gradually over a two year period, even though FDA stated that the composition of the product has been changed repeatedly, the product "has a long history of manufacturing problems," and FDA concluded that the product "has not been reliably potent and stable," even though FDA also emphasized the importance of a precise dose of the drug and the safety risks posed by super-potent or subpotent tablets of levothyroxine.[16] Despite the fact that FDA found that the product was not generally recognized as safe and effective and failed to meet an FDA approval deadline, FDA nonetheless is refraining from taking enforcement action against the product.

Thus, FDA should apply its demonstrated ability to overcome potential obstacles in utilizing its enforcement discretion in the case at hand, which presented legitimate questions regarding compliance with the applicable statutes, poses no safety concerns, and will not affect FDA's policy on exports.[17]

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[13] FDA Guidance for Industry, "Levothyroxine Sodium Products Enforcement of August 14, 2001 Compliance Date and Submission of New Applications," (July 2001).

[14] 62 Fed. Reg. 43535 (Aug. 14, 1997).

[15] 65 Fed. Reg. 2448 (April 26, 2000).

[16] Letter from Dennis E. Baker, Associate Commissioner for Regulatory Affairs, FDA, to Messrs. Dolch and Staffa and Dr. Spigelman (April 26, 2001).

[17] FDA's position provides disincentives to businesses, requiring the maintenance of low inventories of product, and other inefficient practices.

3. Seizure Cases are Entirely Distinguishable

FDA, in its September 10, 2001, letter, compares the case at hand with seizure cases to explain why Pharmanex should not have relied on a federal district court ruling confirming the company's assertions regarding the status of Cholestin® as a dietary supplement. FDA's reference to seizure cases is inapposite. The agency's concern regarding establishing bad precedent in the context of seizure cases if companies violate the law and then avoid negative repercussions by exporting the products is entirely understandable. Permitting the export of seized products under such circumstances would create a disincentive to comply with applicable requirements. However, such a situation is entirely distinguishable from the instant case, in which a company engaged in a legitimate disagreement with FDA regarding its policies and statutory interpretation, and was initially upheld in its position by a federal district court. Pharmanex in good faith raised legitimate issues of statutory interpretation and public policy -- relating to a product that FDA specifically acknowledged in court did not raise safety concerns. Pharmanex did not seek to evade the law and did not require FDA take the burden of initiating a seizure action.

The September 10, 2001, FDA letter cites U.S. v. Kanasco, 123 F.3d 209 (4th Cir. 1997) as support for its argument that permitting the export of Cholestin® would undermine the purposes of the FFDCA. The court in Kanasco noted that, if permitted to export adulterated drugs, in some instances drug manufacturers could "ignore the statutory quality requirements and produce adulterated drugs for sale in the United States, secure in the knowledge that if caught they could claim the export exemption and subsequently find a foreign buyer for the drugs."[18] In addition to the fact that the case involved a seizure, Kanasco is distinguishable from the Pharmanex case in that Pharmanex in no way ignored any statutory requirements applicable to Cholestin ®, but instead ensured that the product met all dietary supplement requirements. Pharmanex was lawfully manufacturing and marketing the product in the U.S. and exporting the product on a regular basis. Pharmanex's actions are in stark contrast to the actions of the manufacturer described in Kanasco. In particular, Pharmanex's request to export its remaining inventory of the product would involve exports to purchasers established and utilized previously, when the product was lawfully sold as a dietary supplement, rather than a post-hoc search for a foreign purchaser referenced in Kanasco.

[18] Id., at 212.

VI. Conclusion

We request a reconsideration of **FDA's** September 10, 2001, conclusion regarding the export of Pharmanex's inventory of Cholestin® and bulk red yeast rice. The inventory should be considered food for export, and satisfies Section Sol(e)(l). In the alternative, if the products are considered unapproved new drugs for purposes of export, the products comply with both Section 801(e)(1) and Section 802. Finally, in light of the unique circumstances, in the alternative we ask that the agency exercise its enforcement discretion to permit the export of the Pharmanex inventory.

Respectfully submitted,

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